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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,666	02/15/2002	Tsuneji Suzuki	054160-5060	7720

9629 7590 12/30/2003  
MORGAN LEWIS & BOCKIUS LLP  
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WASHINGTON, DC 20004

EXAMINER
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PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,666

Applicant(s)

SUZUKI ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Receipt of Papers*

Receipt is acknowledged of the Amendment B, received by the Office September 22, 2003.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 33, and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 847 992 to Suzuki *et al.*.

Suzuki *et al.* teach novel benzamide derivatives. Suzuki *et al.* teach the benzamide derivative claimed by Applicant (see claim 14). Additionally, Suzuki *et al.* teach that the active ingredient may be used in general pharmaceutical compositions, and may be prepared with generally used diluents or excipients, such as binders, extenders, fillers, moisturizers, disintegrants, surfactants, and lubricants. Suzuki *et al.* also teach that the pharmaceutical dosage form can be a tablet, pill, powder, solution, suspension, emulsion, granules, capsule, injection or suppository (page 46, lines 5-15). More specifically, Suzuki *et al.* teach the use of starch, methyl celluloses, calcium carmellose, lactose, sugars, stearates, talc, polyethylene glycol, and many other well known excipients. These teachings anticipate the limitations of Applicant above listed claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki *et al.*, in view of the International Cosmetic Ingredient Dictionary and Handbook.

Suzuki *et al.* are described above as teaching pharmaceutical compositions comprising benzamide derivatives. Suzuki *et al.* teach the inclusion of many well known pharmaceutical excipients.

Suzuki *et al.* does not teach the inclusion of each of the specific excipients claimed by Applicant. Suzuki *et al.* does not teach the inclusion of mannitol as an excipient, hydroxypropyl cellulose as a binder, hydroxypropyl methyl cellulose as a coating agent, or the inclusion of an organic acid salt, an amino compound or an inorganic basic substance. The International Cosmetic Ingredient Dictionary and Handbook is relied upon for the teachings that mannitol and hydroxypropyl cellulose as well known binders, as well as the teaching that hydroxypropyl methyl cellulose is a well known film former. Lastly, the Dictionary and Handbook is relied upon for the teaching that inorganic compounds such as sodium bicarbonate, disodium phosphate, potassium bicarbonate and ammonia, as well as amino compounds such as triethanolamine, diethanolamine, diisopropanolamine, and triisopropanolamine, as well as organic acid salts such as sodium fumarate, and trisodium phosphate are all well known pH

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adjusters. Each of these types of excipients (binders, film formers and pH adjusters) are well known excipients used in the making of pharmaceutical formulations. Therefore, their inclusion in a pharmaceutical composition which allows for necessary excipients is not found to be patentable. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the Applicant's specific selection. One skilled in the art would have been motivated to include the well known excipients discussed above in the compositions described by Suzuki *et al.*. The motivation to do so lies in the teaching of Suzuki *et al.* that well known excipients can be included in their formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that Suzuki doesn't teach the benzamides of formula I combined with the particular additives claimed. The examiner respectfully disagrees. The claims have been rewritten, including many specific additives into independent claim 32. The way the claims are now written, in order to anticipate claim 32, the reference need only teach a benzamide of the same formula as claimed by Applicant in combination with one of the excipients claimed. As discussed in the above rejections, the reference clearly teaches several of the excipients claimed, and therefore still serves as an anticipatory reference. Applicants claim that there is no motivation to use the particular excipients claimed, but this is not true, as the reference clearly teaches some of the particular excipients claimed.

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Furthermore, regarding the obviousness rejection of claim 34, the examiner maintains her position. Absent convincing evidence to the contrary, the selection of a known material based on its suitability for its intended use is obvious to the skilled practitioner.

For these reasons, the rejections are maintained and made final.


### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam  
Patent Examiner  
Art Unit 1615  
December 23, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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